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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,835

10/28/2002

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,835	<b>Applicant(s)</b> ISHIKAWA ET AL.	
	<b>Examiner</b> PATRICIA C. MALLARI	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 21-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/1/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is a non-final Office action. New grounds of rejection are presented which were not necessitated by the applicants' amendments to the claims. The indicated allowability of claims 33 and 34 has regretfully been withdrawn. See the rejections under 35 U.S.C. 101 and 35 U.S.C. 112, set forth below, for details.

#### ***Response to Amendment***

The amendment filed 3/20/07 has been received and entered.

#### ***Information Disclosure Statement***

The information disclosure statement filed in response to the requirement for information under 35 U.S.C. 1.105 has been received and considered.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-13 and 21-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. With regard to claims 1 and 2, despite the addition of certain language to claim 1, the claim still fails to provide a physical transformation or reduction of an article to a different state or thing, wherein the analysis of a result to detect hepatic disease or hepatic cirrhosis constitutes neither a physical transformation nor a reduction of an article to a different state or thing. With

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regard to claims 1-13 and 21-34, the method further fails to set forth a practical application that produces a useful, concrete, and tangible result. In particular, the method fails to set forth a concrete result, in that the specification merely discloses "judging . . . that there is a possibility of suffering from hepatic disease" (see entire specification, especially p. 7). It appears that the method determines merely the possibility that the patient is suffering from a hepatic disease based on the analysis of a result of quantifying isopropanol and/or cyanide. The method does not result in the actual detection of hepatic disease, and therefore does not deliver a concrete result, since the result of a detection of hepatic disease is not necessarily repeatable or predictable. See MPEP 2106.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 and 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 3 recite "to detect a hepatic disease", and claim 21 recites, "to detect hepatic cirrhosis". The applicant's specification indicates that analysis of the quantification of isopropanol and/or cyanide in the breath results not in a detection of

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hepatic disease or hepatic cirrhosis, but in the determination that there is a possibility that a patient suffers from hepatic disease (see entire document, especially p. 7 of the instant specification). Moreover, it appears that the determination of a particular level of isopropanol or cyanide in the breath, while possibly indicating that a patient suffers from a hepatic disease, may also or instead indicate that another disease or condition is present in the patient. Therefore, it is unclear how the claimed method or apparatus results in the detection of a hepatic disease or the detection of hepatic cirrhosis, as claimed, rather than a determination of the possibility that the patient suffers from a hepatic disease or cirrhosis, as described in the specification. One of ordinary skill in the art would be unable to make and/or use the invention as claimed without undue experimentation since the detection of a hepatic disease or cirrhosis based on the analysis of the quantification of isopropanol and/or cyanide is not clearly set forth.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 10, 11, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,221,026 to Phillips in view of "Detection System for Components in Small Amounts of Expired Air" by Chuken et al. (herein referred to as Chuken). Regarding claims 1, 3, and 32, Phillips discloses a breath analyzing apparatus

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and method wherein a breath collecting section is provided for introducing and collecting breath to be analyzed, a breath analyzing section quantifies isopropanol in the breath, and a data processing section analyzes the quantified result obtained by the breath analyzing section (see entire document, particularly col. 10, lines 42-61; col. 13, lines 27-43; col. 14, lines 47-50; col. 20, line 22 of Phillips). Phillips analyzes the quantification of isopropanol in the breath to detect the presence of one or more diseases in the patient, wherein the detection of the presence of disease utilizes the natural phenomenon of particular isopropanol levels in the breath of patients having particular diseases (see entire document, especially col. 15, line 8-col. 17, line 45; Table 2 of Phillips). Phillips does not specify hepatic or liver disease as one of these diseases.

However, Chuken discloses a patient having liver disease exhibiting a particular, abnormal level of breath component and further discloses quantifying breath components and correlating the quantification with the presence of liver disease in a patient (see entire document, especially fig. 6 and section 4 of Chuken). Therefore, since the detection of a disease utilizing the quantification of isopropanol in the breath is known, as shown by Phillips, the quantification of a breath component to detect liver disease is also known, as shown by Chuken, and the particular correlation between a particular breath component (isopropanol) and the presence of liver disease in the patient is nothing more than a natural phenomenon, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Chuken, with

that of Phillips, in light of this natural phenomenon, for the predictable result of enabling the detection of liver disease by quantification of isopropanol.

Regarding claims 4, 5, and 11, the breath collecting section consists of a breath collecting means and a breath transfer means (see entire document, especially col. 10, lines 41-59 of Phillips).

Regarding claim 10, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 66-67 of Phillips).

Claims 1-5, 10, 11, 21-23, 28, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,221,026 to Phillips in view of US Patent No. 4,772,559 to Preti et al. Regarding claims 1-3, 21, and 32, Phillips discloses a breath analyzing apparatus and method wherein a breath collecting section is provided for introducing and collecting breath to be analyzed, a breath analyzing section quantifies isopropanol in the breath, and a data processing section analyzes the quantified result obtained by the breath analyzing section (see entire document, particularly col. 10, lines 42-61; col. 13, lines 27-43; col. 14, lines 47-50; col. 20, line 22 of Phillips). Phillips analyzes the quantification of isopropanol in the breath to detect the presence of one or more diseases in the patient, wherein the detection of the presence of disease utilizes the natural phenomenon of particular isopropanol levels in the breath of patients having particular diseases (see entire document, especially col. 15, line 8-col. 17, line 45; table of Phillips). Phillips does not specify hepatic or liver disease as one of these diseases.

However, Preti discloses a patient having hepatic cirrhosis exhibiting a particular, abnormal level of breath component and further discloses quantifying breath components and correlating the quantification with the presence of hepatic cirrhosis in a patient (see entire document, especially col. 1, line 52-col. 2, line 7 of Preti). Therefore, since the detection of diseases utilizing the quantification of isopropanol in the breath is known, as shown by Phillips, the quantification of a breath component to detect hepatic cirrhosis is also known, as shown by Preti, and the particular correlation between a particular breath component (isopropanol) and the presence of liver disease in the patient is nothing more than a natural phenomenon, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Preti, with that of Phillips, in light of this natural phenomenon, for the predictable result of enabling the detection of hepatic cirrhosis by quantification of isopropanol.

Regarding claims 4, 5, 11, 22, 23, and 29 the breath collecting section consists of a breath collecting means and a breath transfer means (see entire document, especially col. 10, lines 41-59 of Phillips). With further regard to claim 23, the breath collecting means is a mouthpiece (see entire document, especially col. 10, lines 53-55 of Phillips).

Regarding claims 10 and 28, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 66-67 of Phillips).

Claims 6-9, 12, 13, 24-27, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips in view of Preti, as applied to claims 1-5, 10, 11, 21-23, 28, 29, and 32, above, and further in view of US Patent No. 5,573,005 to Ueda. Phillips,



as modified, describes a system having a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph, but fails to describe the system, particularly the breath collection apparatus in detail. However, Ueda, discloses a heated, portable, microprocessor-controlled breath collection apparatus and gas chromatograph for collecting and analyzing expiration from a user (see entire document, especially fig. 1; col. 2, line 46-col. 3, line 65; col. 4, lines 11-26 of Ueda). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the portions of the system of Ueda as that of Phillips, as modified, since Phillips teaches using a system comprising a breath collection apparatus and gas chromatograph, and Ueda describes such a system.

Regarding claims 6 and 24, the breath collecting means is a communicating opening for connecting a breath container 12 (see entire document, especially fig. 1; col. 5, lines 1-35 of Ueda).

Regarding claims 7-9, 12, 13, 25-27, 30, and 31, the breath transfer means comprises a duct that connects the breath collecting means 4, 6, 8 with the breath analyzing section 14 (see entire document, especially fig. 1; col. 5, lines 24-30 of Ueda). With further regard to claims 8 and 26, the breath transfer means further includes a pump means (piston of syringe 12 and motor 12) to send breath to the breath analyzing section (see entire document, especially col. 5, lines 17-30 of Ueda). With further regard to claims 9, 13, and 27, the breath collecting means includes a mouthpiece 8 (see entire document, especially col. 5, lines 1-2 of Ueda), a communicating opening for connecting a breath container 12 (see entire document, especially fig. 1 of Ueda), and

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valve means 10 which can be switched so that only one of the mouthpiece and the breath container 12 communicates with the breath analyzing section 15 (see entire document, especially col. 15, lines 17-30 of Ueda). With further regard to claims 12, 13, 30, and 31, the breath analyzing section comprises a mass spectrometer (see entire document, especially col. 10, lines 65-67 of Phillips).

### ***Response to Arguments***

Applicant's arguments with respect to the prior art have been considered but are moot in view of the new ground(s) of rejection.

As to the rejection of claims 1 and 2 under 35 U.S.C. 101, the applicants did not address the rejection except to note that amendments were made to the claims to obviate the rejection. Unfortunately, these amendments were not sufficient to overcome the rejection. See the rejection set forth above.

### ***Allowable Subject Matter***

No prior art has been applied to claims 33 and 34. In light of the rejections under 35 U.S.C. 101 and 112, 1st paragraph, set forth above, no statement of allowability is being given at this time. Upon resolution of these issues, the prior art will be revisited. However, at this time, the prior art of record fails to teach the claimed breath analyzing apparatus wherein at least cyanides in the breath are quantified or wherein both isopropanol and cyanides in the breath are quantified.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
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/P. C. M./  
Examiner, Art Unit 3735